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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Applicant : Robert Shorr et al.
Serial No. : 10/047,802
Filed : January 16, 2002
For : PROSTACYCLIN DERIVATIVE
CONTAINING COMPOSITIONS AND
METHODS OF USING THE SAME FOR
THE TREATMENT OF CANCER
Examiner : Jerome D. Goldberg
Art Unit : 1614
Attorney Docket No. : 732.1.010

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I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450
ON September 23, 2003

NAME Jill S. Garretson

SIGNATURE *Jill S. Garretson*

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

September 23, 2003

RESPONSE

Dear Sir:

This is in response to the Office Action of March 26, 2003. Applicants have filed concurrently herewith a Petition for a three month extension of time along with the requisite fee extending the date for response to September 26, 2003.

Page 2 of the Office Action sets forth a prospective objection to the claims in that if claims 1-4 were found allowable, other claims in the application may be objected to under 37 C.F.R. Section 1.75 as being a substantial duplicate thereof. Since claims 1-4 have not yet been indicated as allowable, no further action on part of Applicant to the prospective objection is deemed proper at this time.

Claims 1-10 and 22-28 stand rejected as obvious over Tadepalli et al. on the ground that the reference teaches Applicant's pharmaceutical formulations suitable for a variety of administrations. The Office Action states that one skilled in the art would find ample motivation to prepare a pharmaceutical compound of the prior art with reasonable expectation at said composition would be effective as a pharmaceutical composition and that the intended use of the pharmaceutical composition carries no weight. This ground of rejection is deemed improper and withdrawal of the same is respectfully requested.

Antidepressant amount of 100 mg

The present invention is directed to pharmaceutical compositions for the treatment of cancer. Not only do the compositions require the active ingredient of Formula I, but also require a cancer-treating effective amount of the same. Quite clearly, the prior art references of record do not teach a composition for the treatment of cancer nor any motivation on the part of one of ordinary skill in the art to employ the composition in a cancer-treating effective amount for the treatment of cancer. There is no motivation to provide a cancer-treating effective amount because the prior art is silent as to the treatment of cancer. The only way the one would be motivated to employ a cancer-treating effective amount is to have the

benefit of Applicant's disclosure herein for this purpose. Such hindsight reconstructions does not support a rejection based on obviousness.

Claims 1-28 stand rejected under 35 U.S.C. Section 112 on the grounds that the specification does not provide enablement for the term "cancer". This ground of rejection is deemed improper and withdrawal of the same is respectfully requested.

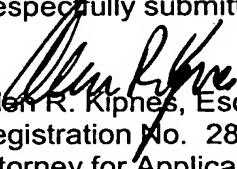
Page 25 of the specification identifies a non-exhaustive list of cancers that may be treated in accordance with the present invention including lung, liver, brain, pancreatic, kidney, prostate, breast, colon and head-neck cancers. Because the present composition can affect cancers in a variety of ways (see the present specification beginning at the top of page 17) including inhibiting metastasis, inhibiting protein degradation, promoting apoptosis and controlling cell proliferation, one can reasonably conclude that a wide range of cancers can be affected by treatment with the present composition. In addition, Applicants have provided data beginning with Example 1 on page 27 of the specification showing the ability of a present composition to attack cancer cells in a variety of ways. In view of the foregoing, Applicants submit that the term "cancer" is enabled in the present application and withdrawal of the rejection of the 35 U.S.C. Section 112 is deemed proper and is respectfully requested.

Applicants therefore submit that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

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It is believed that no fee is due, however, if any fee is due it should be charged to Deposit Account No. 23-0510.

Respectfully submitted,


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